

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

**INFORMATION SUBMISSION UNDER
MPEP §724.02**

Docket Number

Application Number
09/606,629

Filing Date
June 29, 2000

Examiner
To Be
Assigned

Art Unit
1615

Invention Title
**CONTROLLED ABSORPTION DILTIAZEM
PHARMACEUTICAL FORMULATION**

Inventor(s)
Heinicke et al.

Assistant Commissioner for Patents
Washington, D.C. 20231

**DISCLOSURE OF INFORMATION SUBJECT TO A
PROTECTIVE ORDER**

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56 and in conformance with the procedures of M.P.E.P. § 724.02, attorneys for Applicants hereby disclose the following materials, copies of which are enclosed under seal. This confidential information is presented subject to the terms of a Stipulated Order Modifying Protective Order, entered in *Purepac Pharmaceutical Co. v. Andrx Pharmaceuticals, Inc.*, civil action no. 00-CV-1224, pending in the United States District Court for the Eastern District of Pennsylvania. A copy of the Stipulated Protective Order, and the Protective Order it modifies, is attached herewith.

It is respectfully requested that the following information submitted under seal be expressly considered during the prosecution of this application:

- 1.) Deposition Transcript of Chih-Ming Chen, November 17, 2000
Purepac Pharmaceutical Co. v. Andrx Pharmaceuticals, Inc.
Civil Action No. 00-1224
U.S. District Court for the Eastern District of Pennsylvania
175 pages
- 2.) Laboratory Notebooks of Chih-Ming Chen (3), bearing production numbers nos. 116295-480, 116482-613, and 116615-674.

Table of Relevant Data - 3 pages
- 3.) Applicants' Remarks prepared in connection with items (1) and (2).

Respectfully submitted,

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U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

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MATERIAL SUBJECT TO PROTECTIVE ORDER
NOT OPEN TO PUBLIC
TO BE VIEWED ONLY BY EXAMINER OR OTHER
AUTHORIZED PATENT AND TRADEMARK OFFICE EMPLOYEE

Sir:

The following remarks are submitted by Applicants to assist in the consideration of the materials submitted herewith. Applicants enclose:

- 1.) The transcript of the deposition of Chih-Ming Chen (November 17, 2000) and
- 2.) Laboratory notebooks of Chih-Ming Chen produced by defendant in the litigation referenced on each document.

Applicants have also prepared tables, submitted herewith, summarizing relevant data culled from the laboratory notebook pages on the dissolution of long lag pellets identified in the notebooks.

Based on the deposition testimony of Chih-Ming Chen, Applicants note that the laboratory notebook pages disclose an analysis of Cardizem CD and a series of experiments seeking to duplicate the *in vitro* dissolution profile of that product using an active core containing no organic acid. The various formulations tested by Dr. Chen employed two types of pellets, an "SR1" pellet that would dissolve rapidly after a relatively brief delay, and a second "SR2" pellet with a longer lag time. The long lag pellets produced by Dr. Chen in these experiments exhibited a dissolution profile in an acidic solution substantially different than that required by the present invention. The tabulated dissolution profile data demonstrate the differences.

Furthermore, Applicants assert that the Chen laboratory notebook disclosure is cumulative of U.S. 5,567,441, previously disclosed in connection with a parent application to the present application.

Respectfully submitted,

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